

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION;
STATE OF NEW YORK; STATE OF
CALIFORNIA; STATE OF ILLINOIS;
STATE OF NORTH CAROLINA; STATE
OF OHIO; COMMONWEALTH OF
PENNSYLVANIA; and
COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC;
PHOENIXUS AG; MARTIN SHKRELI,
individually, as an owner and former director
of Phoenixus AG and a former executive of
Vyera Pharmaceuticals, LLC; and KEVIN
MULLEADY, individually, as an owner and
director of Phoenixus AG and a former
executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No. 1:20-cv-00706-DLC

[Proposed] Joint Pretrial Order

The Federal Trade Commission (“FTC”), State of New York, State of California, State of Illinois, State of North Carolina, State of Ohio, Commonwealth of Pennsylvania, and Commonwealth of Virginia (collectively, “State Plaintiffs,” and, together with FTC, “Plaintiffs”), Defendants Vyera Pharmaceuticals, LLC and Phoenixus AG (the “Company Defendants”), Defendant Martin Shkreli, and Defendant Kevin Mulleady (the “Individual Defendants,” and collectively with the Company Defendants, “Defendants”), by their undersigned counsel, hereby jointly submit this Pretrial Order in accordance with the Court’s Order dated April 1, 2021 (ECF No. 409) and the Court’s Individual Practices in Civil Cases (effective April 1, 2021).

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2. Jurisdiction

Plaintiffs:

This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because it arises under federal law, 28 U.S.C. § 1337(a) (statutes regulating commerce and trade) and 28 U.S.C. § 1345 (federal government plaintiff), as well as under the principles of supplemental jurisdiction codified in 28 U.S.C. § 1367(a).

Defendants:

Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

3. Claims and Defenses

PLAINTIFFS

Claims

Plaintiffs' Summary of Claims:

All Plaintiffs' claims remain to be tried:

1. Defendants' multi-faceted scheme to prevent competition to Daraprim constitutes unlawful monopoly maintenance.¹
2. Defendant Martin Shkreli is individually liable for this multi-faceted scheme based on his participation in, and direction of, the violation and his authority to control the corporation.²

¹ Section 2 of the Sherman, 15 U.S.C. § 2, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), New York's Donnelly Act, New York Business Law § 340 *et seq.*, Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Act, N.C. Gen. Stat. § 75-1 *et seq.*, Ohio's Valentine Act, codified in Ohio Rev. Code § 1331, and the Virginia Antitrust Act, Virginia Code § 59.1-9.6.

² Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), New York's Donnelly Act, New York Business Law § 340 *et seq.*, Illinois Antitrust Act, 740

3. Defendant Kevin Mulleady is individually liable for this multi-faceted scheme based on his participation in, and direction of, the violation and his authority to control the corporation.³

4. Defendants' agreements with distributors, hospitals, and other downstream purchasers barring them from reselling Daraprim to potential generic competitors constitute unreasonable restraints of trade.⁴

5. Defendants' exclusive pyrimethamine API contracts with Fukuzyu and RL Fine constitute unreasonable restraints of trade.⁵

ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Act, N.C. Gen. Stat. § 75-1 *et seq.*, Ohio's Valentine Act, codified in Ohio Rev. Code § 1331, and the Virginia Antitrust Act, Virginia Code § 59.1-9.6.

³ Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), New York's Donnelly Act, New York Business Law § 340 *et seq.*, Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Act, N.C. Gen. Stat. § 75-1 *et seq.*, Ohio's Valentine Act, codified in Ohio Rev. Code § 1331, and the Virginia Antitrust Act, Virginia Code § 59.1-9.6.

⁴ Section 1 of the Sherman Act, 15 U.S.C. § 1, unfair methods of competition in competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), New York's Donnelly Act, New York Business Law § 340 *et seq.*, California's Cartwright Act, California Business and Professions Code § 16700 *et seq.*, California's Unfair Competition Act, California Business and Professions Code § 17200 *et seq.*, Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Act, N.C. Gen. Stat. § 75-1 *et seq.*, Ohio's Valentine Act, codified in Ohio Rev. Code § 1331, Pennsylvania's Common Law Doctrine Against Restraint of Trade, and the Virginia Antitrust Act, Virginia Code § 59.1-9.5.

⁵ Section 1 of the Sherman Act, 15 U.S.C. § 1, unfair methods of competition in competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), New York's Donnelly Act, New York Business Law § 340 *et seq.*, California's Cartwright Act, California Business and Professions Code § 16700 *et seq.*, California's Unfair Competition Act, California Business and Professions Code § 17200 *et seq.*, Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Act, N.C. Gen. Stat. § 75-1 *et seq.*, Ohio's Valentine Act, codified in Ohio Rev. Code § 1331, Pennsylvania's Common Law Doctrine Against Restraint of Trade, and the Virginia Antitrust Act, Virginia Code § 59.1-9.5.

6. Defendants' repeated and persistent illegal acts in violation of Sections 1 and 2 of the Sherman Act and section 340 *et seq.* of the Donnelly Act constitute a violation of § 63(12) of New York's Executive Law.

The following claim is not to be tried:

1. The Court dismissed Plaintiff Commonwealth of Pennsylvania's previously asserted claim under Pennsylvania's Unfair Trade Practices and Consumer Protection Law (ECF 229).

All Plaintiffs maintain the following prayers for relief:

1. Issue a declaratory judgment that Defendants' course of conduct and agreements in restraint of trade violate federal and state law.⁶

2. Permanently enjoin Defendants from continuing their course of conduct and from engaging in similar and related conduct in the future.

3. Permanently enjoin Shkreli and Mulleady from owning in part or whole or working for a company engaged in the pharmaceutical industry.

⁶ Section 2 of the Sherman Act, 15 U.S.C. § 2; Section 1 of the Sherman Act, 15 U.S.C. § 1; ; Section 5(a) of the FTC Act, 15 U.S.C. § 45(a); New York's Donnelly Act, N.Y. GBL § 340 *et seq.*; New York's Executive Law, N.Y. § 63(12); California's Cartwright Act, CA Bus & Prof Code § 16700 *et seq.*, and California's Unfair Competition Act, CA Bus & Prof Code § 17200 *et seq.*; Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*; North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*; Ohio's Valentine Act; Ohio Revised Code Chapter 1331; Pennsylvania's Common Law Doctrine against Restraints of Trade; and Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq.*

The State Plaintiffs maintain the following prayers for relief:

1. Such other equitable relief, including equitable monetary relief, as the Court finds necessary to redress and deter recurrence of Defendants' violations of federal and state law.⁷
2. An award of reasonable attorneys' fees and costs to the State Plaintiffs.

Dropped prayers for relief:

1. The Court dismissed the FTC's request for equitable monetary relief (ECF 453).
2. The State Plaintiffs withdrew their request for civil penalties/forfeitures (ECF 408).

Plaintiffs' Response to Defendants' Summary of Defenses

Defenses previously struck: The following defenses asserted by Corporate Defendants and Shkreli in their answers to the Amended Complaint were struck (ECF 365) and are not to be tried:

1. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not alleged that Vyera or Shkreli is presently engaged in ongoing violations of law, as required by, *inter alia*, Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), and New York Executive Law Section 63(12), N.Y. Exec. Law § 63(12). (Corporate Defendants' Fourth Affirmative Defense (ECF 254); Shkreli's Fourth Affirmative Defense (ECF 259)).

⁷ Section 1 of the Sherman Act; Section 2 of the Sherman Act; New York's Donnelly Act, New York Executive Law § 63(12); California's Cartwright Act, Ca Bus & Prof Code § 16700 *et seq.*; California's Unfair Competition Act, CA Bus & Prof Code § 17200; Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*; North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.*; Ohio's Valentine Act, Ohio Rev. Code Chapter 1331; Pennsylvania Common Law Doctrine against Restraints of Trade; and Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq.*

2. Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli did not enter into or sign any agreements with any distributors, hospitals, other downstream purchasers, or any API suppliers. (Shkreli's Thirteenth Affirmative Defense).

3. Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli, as an individual, does not possess any market power or monopoly power. (Shkreli's Fifteenth Affirmative Defense).

Defenses dropped by Defendants: Defendants appear to no longer assert the following defenses previously asserted in their respective Answers to the Amended Complaint and, therefore, they are not to be tried:

1. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or the doctrine of laches. (Corporate Defendants' Second Affirmative Defense; Shkreli's Second Affirmative Defense; Mulleady's Thirteenth Affirmative Defense (ECF 257)).

2. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs are not direct purchasers of Daraprim, and have not suffered any antitrust injury. (Shkreli's Fourteenth Affirmative Defense; Mulleady's Ninth Affirmative Defense).

3. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack standing to assert them. (Shkreli's Nineteenth Affirmative Defense; Mulleady's Second Affirmative Defense).

4. Plaintiffs' claims are barred, in whole or in part, because Defendant's conduct was justified, privileged, and/or not improper. (Shkreli's Twenty-First Affirmative Defense; Mulleady's Eighth Affirmative Defense).

DEFENDANTS

Defendants' Summary of Claims:

Defendants identify the following claims brought by Plaintiffs under federal and state law that remain to be tried:

- Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 5(a) of the FTC Act, 15 U.S.C. § 45(a) [Count I of Amended Complaint (ECF No. 87)];
- Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 5(a) of the FTC Act, 15 U.S.C. § 45(a) [Counts II and III of Amended Complaint];
- New York's Donnelly Act, New York Gen. Bus. Law § 340 *et seq.*, and New York Executive Law § 63(12) [Counts IV.A and IV.B, respectively, of Amended Complaint];
- California's Cartwright Act, Cal. Bus. & Prof. Code § 16700 *et seq.*, and California's Unfair Competition Act, Cal. Bus. & Prof. Code § 17200 *et seq.* [Counts V.A and V.B, respectively, of Amended Complaint];
- Illinois Antitrust Act, 740 ILCS 10/1 *et seq.* [Count VI of Amended Complaint];
- North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 *et seq.* [Count VII of Amended Complaint];
- Ohio's Valentine Act, Ohio Rev. Code Chapter 1331 *et seq.* [Count VIII of Amended Complaint];
- Pennsylvania's Common Law Doctrine Against Restraints of Trade [Count IX.B of Amended Complaint]; and
- Virginia Antitrust Act, Virginia Code § 59.1-9.1 *et seq.* [Count X of Amended Complaint].

Plaintiffs' claim under the Pennsylvania Unfair Trade Practices and Consumer Protection

Law [Count IX.A of the Amended Complaint] was previously dismissed. (ECF No. 229.)

Plaintiffs request the following relief:

- Declaratory relief for the FTC and the State Plaintiffs (Amended Complaint, Prayer for Relief ¶¶ 1-12);
- Injunctive relief for the FTC and the State Plaintiffs (*id.* ¶¶ 13-15);
- Equitable monetary relief (*id.* ¶¶ 16-17) for only the State Plaintiffs. The Court dismissed FTC's request for equitable monetary relief. (ECF No. 453); and
- Reasonable attorneys' fees and costs for only the State Plaintiffs (Amended Complaint, Prayer for Relief ¶ 18).

The State Plaintiffs withdrew with prejudice their request for civil penalties/forfeitures. (ECF No. 408.)

Defendants' Summary of Defenses:

The following defenses remain to be tried:

- As to each defendant, whether Plaintiffs carried their burden to prove each element of their claims;
- As to each defendant, whether Plaintiffs properly defined the relevant product market as consisting of "FDA-approved pyrimethamine products";
- As to each defendant, whether Plaintiffs carried their burden to prove that the challenged conduct caused a substantial anticompetitive effect that harmed consumers;
- As to each defendant, whether Plaintiffs proved that the challenged conduct resulted in substantial foreclosure of the market for pyrimethamine API;
- As to each defendant, whether Plaintiffs proved that Defendants violated a duty to

deal;

- As to each defendant, whether Plaintiffs proved that Defendants engaged in concerted anticompetitive conduct;
- As to each defendant, whether the conduct challenged by Plaintiffs has a procompetitive justification that outweighs any alleged anticompetitive harm;
- As to the Individual Defendants, whether Plaintiffs carried their burden of proving that the Individual Defendants can be held liable for any alleged anticompetitive conduct;
- As to each defendant, whether Plaintiffs carried their burden of proving that they are entitled to equitable monetary relief, and the amount of such relief; and
- As to each defendant, whether Plaintiffs have demonstrated that an injunction is permitted or needed to remedy ongoing or threatened anticompetitive conduct that is likely to reoccur.

4. Estimated Trial Length

Plaintiffs estimate they will require 29 hours of trial time. Defendants estimate they will require 35 hours of trial time.

Assuming that the Court's schedule allows for approximately five and half hours of testimony per day, the requested total trial time would require between 11 and 13 trial days, not including openings and closings.

The case is to be tried without a jury.

5. Trial by a Magistrate Judge

The parties do not consent to trial by a magistrate judge.

6. Stipulations of Fact and Law

The stipulations of fact and law agreed to by all parties are set forth in Attachment A.

7. Trial Witnesses

Plaintiffs' trial witnesses and a brief summary of the substance of each witness's testimony are set forth in Attachment B-1. Defendants' trial witnesses and a brief summary of the substance of each witness's testimony are set forth in Attachment B-2. The witness lists indicate whether each witness will testify live or by deposition.

8. Deposition Designations

Plaintiffs' designations of testimony to be offered in their case in chief are listed in Attachment C-1. Defendants' designations of testimony to be offered in their case in chief are listed in Attachment C-2. The designation lists also include counter-designations and objections made by other parties.

9. Trial Exhibits

Plaintiffs' exhibits to be offered in their case in chief are listed in Attachment D-1. Defendants' exhibits to be offered in their case in chief are listed in Attachment D-2. The lists of exhibits indicate exhibits to which no party objects on the grounds of authenticity with one star and exhibits to which no party objects on any ground with two stars.

IT IS SO ORDERED this _____ day of _____, 2021.

Denise Cote
UNITED STATES DISTRICT JUDGE

Respectfully submitted and agreed,

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